UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FARUQI & FARUQI, LLP, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 1:18-cv-3140

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

1. This is an action brought under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, to compel the release of agency records of the United States Food and Drug Administration (the "FDA" or "Defendant") concerning Synergy Pharmaceuticals, Inc.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue lies in this district under 5 U.S.C. § 552(a)(4)(B).

PARTIES

3. Plaintiff, Faruqi & Faruqi, LLP (the "Faruqi Firm" or "Plaintiff"), is a law firm with an office in New York, New York. The Faruqi Firm is the requestor of the withheld documents and records described in Plaintiff's March 8, 2018 FOIA request (the "FOIA Request"), a copy of which is attached hereto as Exhibit 1.

4. Defendant, the FDA, is an agency of the Executive Branch of the United States federal government. The FDA is an "agency" within the meaning of 5 U.S.C. § 552(f)(1), located within the Department of Health and Human Services, and charged with responsibility

for, *inter alia*, protecting the public health by assuring that human drugs, vaccines, and other biologic products and medical devices intended for human use are safe and effective, and that prescription drug advertising is truthful and not misleading.

STATEMENT OF FACTS

5. On March 8, 2018, Plaintiff electronically filed the FOIA Request on the FDA's website seeking access to "copies of all documents . . . concerning the National Advertising Division's (the "NAD") case *Allergan, Inc. v. Synergy Pharmaceuticals, Inc.*, NAD Case No. 6130: Trulance" and "copies of all documents . . . regarding any comparison of Trulance (plecanatide) to Amitiza (lubiprostone) or Linzess (linaclotide) in any clinical trial, advertisement, promotional label, or prescribing information."[1] *See* Exhibit 1. That same day, Plaintiff received an automatically generated confirmation number FDA1841970.

6. On March 15, 2018, Plaintiff also received an automatically generated e-mail from the FDA assigning the FOIA Request a reference number 2018-2143.

7. Pursuant to 5 U.S.C. § 552(a)(6)(A)(i), Defendant was required to respond to Plaintiff's FOIA within twenty (20) working days, or by April 5, 2018.

8. To date, Defendant has failed to make any determination regarding Plaintiff's FOIA request or to produce any records in response to that request.

9. Since Defendant has failed to comply with the time limits set forth in 5 U.S.C. § 552(a)(6)(A) and 5 U.S.C. § 552(a)(6)(B), Plaintiff is deemed to have exhausted all administrative remedies with respect to its FOIA Request pursuant to 5 U.S.C. § 552(a)(6)(C) and agency regulations.

[1] Unless otherwise noted, all internal citations and quotations are omitted and all emphases are added.

10. Plaintiff has a statutory right to the disclosure of the documents and records described in the FOIA Request, and there is no legal basis for the FDA's failure to respond in a timely manner.

COUNT I

Violation of the FOIA: Failure to Comply with Statutory Deadlines

11. Plaintiff re-alleges each allegation above as if fully set forth herein.

12. The FDA's failure to make a determination and/or produce records in response to the FOIA Request violated the statutory deadlines imposed by the FOIA, including the deadline set forth in 5 U.S.C. §§ 552(a)(6)(A) and 552(a)(6)(B).

13. Plaintiff has exhausted the applicable administrative remedies with respect to Plaintiff's FOIA Request.

14. Plaintiff is entitled to injunctive relief compelling the release and disclosure of the requested agency records.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

a) Declaring that Defendant's failure to disclose the documents and records described in the FOIA Request is unlawful;

b) Ordering Defendants to make the documents and records described in the FOIA Request available to Plaintiff;

c) Awarding Plaintiff its costs and attorneys' fees; and

d) Awarding Plaintiff such other relief as the Court may deem just and proper.

Dated: April 10, 2018

Respectfully submitted,

FARUQI & FARUQI, LLP

By: *__/s/ Richard W. Gonnello__*

Richard W. Gonnello

Richard W. Gonnello
Sherief Morsy
685 Third Avenue, 26th Floor
New York, NY 10017
Ph: (212) 983-9330
Fx: (212) 983-9331
E-mail: rgonnello@faruqilaw.com
smorsy@faruqilaw.com

Attorneys for Plaintiff

EXHIBIT 1

FARUQI & FARUQI LLP
ATTORNEYS AT LAW
NEW YORK CALIFORNIA DELAWARE PENNSYLVANIA

March 8, 2018

VIA ELECTRONIC SUBMISSION

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Re: Freedom of Information Request

To Whom It May Concern:

I write to request records pursuant to the Freedom of Information Act, 5 U.S.C. § 552 *et seq.*, as amended ("FOIA").

First, I request that the FDA provide me with copies of all documents in the FDA's possession concerning the National Advertising Division's (the "NAD") case *Allergan, Inc. v. Synergy Pharmaceuticals, Inc.*, NAD Case No. 6130: Trulance. For reference, a copy of the NAD Case Report is enclosed.

Second, I request copies of all documents in the FDA's possession regarding any comparison of Trulance (plecanatide) to Amitiza (lubiprostone) or Linzess (linaclotide) in any ***clinical trial, advertisement, promotional label, or prescribing information***.[1]

If access to any of the requested records is denied, FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. I therefore request that I be provided with all non-exempt portions which are reasonably segregable. I further request that you describe the deleted material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies in this instance. Please separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. I, of course, reserve the right to appeal the withholding or deletion of any information.

I am willing to pay fees for this request up to a maximum of $500.00. If you estimate that the fees will exceed this limit, please inform me first.

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[1] Trulance (NDA # 208745) is manufactured by Synergy Pharmaceuticals. Amitiza (NDA # 021908) is manufactured by Sucampo Pharma. Linzess (NDA # 202811) is manufactured by Allergan. I request information pursuant to the definitions of "advertisement", "promotional labeling", and "prescribing information" found on the FDA's website. *See* "Drug Advertising: A Glossary of Terms", available at https://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#promotional_labeling

Access to the records should be granted within twenty (20) business days from the date of your receipt, as the statute requires. Failure to respond in a timely manner shall be viewed as a denial of this request and the requester may immediately file an administrative appeal.

Thank you in advance of your prompt reply. If you have any questions processing this request, please contact me at (212) 983-9330.

Sincerely,

Richard W. Gonnello

Enclosure: NAD Case Report for NAD Case #6130.

Case #6130 *(11/01/2017)*

SYNERGY PHARMACEUTICALS, INC.

Trulance

Challenger: *Allergan, Inc.*
Product Type: *Drugs / Health / Health Aids*
Issues: *Health & Safety Claims; Comparative Performance Claims*
Disposition: *Referred to Government Agency*

Basis of Inquiry: Claims made by Synergy Pharmaceuticals, Inc. ("Synergy" or "the advertiser") in online, medical journals, and printed waiting room advertising, as well as through in-person detailing, for its Trulance Chronic Idiopathic Constipation prescription drug were challenged by Allergan, Inc. ("Allergan" or "the challenger"), maker of the competing drug, Linzess. The following are representative of the claims that served as the basis for NAD's inquiry:

Express Claims:

"You shouldn't have to go to extremes for your Chronic Idiopathic Constipation."

"Diarrhea isn't the goal of constipation relief. It's a compromise."

"New once-daily Trulance may provide more regular, well-formed bowel movements for adults with Chronic Idiopathic Constipation (CIC)."

"Going shouldn't mean going to extremes."

"Diarrhea is not efficacy – it's time to address the age-old tradeoff in CIC."

"Now there's Trulance, the only treatment that is thought to replicate the pH-sensitivity of naturally occurring uroguanylin."

"Trulance provided more regular, well-formed bowel movements."

Implied Claims:

Trulance can be used without the risk of diarrhea.

Trulance is superior to Linzess.

Challenger's Position:

I. Implied Claim that Trulance Does Not Cause Diarrhea Is False

Allergan argued that claims like: "Diarrhea is not the goal of constipation relief. It's a compromise" and "Diarrhea is not efficacy," communicate the false message that Trulance will not cause the "extreme" result of diarrhea. According to the challenger, Synergy's advertising suggests Trulance can provide "more regular, well-formed bowel movements," and implies that that this product will not cause diarrhea.

The challenger explained that Synergy is required to identify a risk of diarrhea on its Food and Drug Administration (FDA) approved product labeling due to the incidence of diarrhea and severe diarrhea observed in its clinical trials. Although Synergy's advertisements disclose in small font that diarrhea is, in fact, the most common adverse reaction to treatment with Trulance (as required by law), the challenger contended these disclaimers do not adequately correct the false implication that Trulance is a treatment option that allows patients to avoid diarrhea.

II. Claim that Trulance Is Superior to Linzess Is Not Substantiated

Allergan asserted the clear implication of the phrases, "Going shouldn't mean going to extremes" or "You shouldn't have to go to extremes for your Chronic Idiopathic Constipation," in the context of the challenged advertising, is that patients taking the market-leading competitor Linzess will experience extremes in the form of diarrhea, while those taking Trulance will not. Moreover, the comparative claim that Trulance provides "more regular, well-formed bowel movements" also conveys superiority over competitive treatments. The challenger further noted the tiny footnote clarifying the comparison against a placebo does little to correct the misleading implied comparison to competing treatments.

The challenger contended these superiority claims are unsubstantiated. Allergan explained that the FDA, the only entity with access to the full clinical data for both drugs, states repeatedly in its Trulance approval documents that "[t]he safety profile of plecanatide [Trulance] is similar to linaclotide [Linzess]." Allergan also observed that head-to-head testing of Trulance against Linzess has not been conducted. In short, the challenger argued without data comparing these products on the same criteria under the same conditions, Synergy should not be permitted to imply superiority over Linzess.

III. In-Person Detailing Reflects Unsubstantiated Express Superiority Claims

Allergan argued that Synergy's in-person detailing with healthcare professionals also involved explicit superiority claims against Linzess, which were unsubstantiated. These statements by Trulance marketing representatives include, for example: "The cost is similar to Linzess, the competitor. It has a much lower rate of diarrhea, about 5 percent," "lesser incidence of diarrhea compared to Linzess," and "works similarly to Linzess, but has fewer side effects."

IV. Undisclosed Native Advertising Claims are False

The challenger maintained that Synergy's "Guide to CIC" is a promotional waiting room pamphlet commissioned by Synergy to bring the brand's message to condition sufferers. The content in the Guide recommends Trulance by advising patients: "It may be time to try something new" and to "[a]sk your doctor if this option makes sense for you." Notwithstanding that the Guide is commissioned, paid-for and distributed by Synergy, Allergan noted the Guide does not disclose that it is, in fact, advertising material. Instead, it misleadingly suggests to patients that it is a source of independent and impartial patient education.

Additionally, the challenger stated that the Guide also includes false claims, such as "Now there's a treatment that treats constipation without causing diarrhea." Furthermore, Allergan maintained that the claim "many people who tried prescription options to treat their constipation complained that they led to diarrhea" is a disparaging and unsubstantiated superiority claim. Finally, Allergan refuted claims that: "Trulance replicates what your body does naturally," "is designed to work like a natural peptide in your body called uroguanylin," and "Trulance replicates the activity of human uroguanylin." The challenger contended that Trulance is a synthetic molecule with unique properties and does not replicate a natural process in the body. Moreover, Allergan asserted that the advertiser has no clinical data that supports these scientific claims.

Advertiser's Position:

The advertiser chose not to participate in this NAD proceeding. Synergy denied Allergan's characterization of its advertising, which was developed in accordance with the requirements of the federal Food, Drug and Cosmetic Act and FDA rules, regulations and guidance. The advertiser contended that the FDA has primary jurisdiction for the advertising and promotion for prescription pharmaceutical products and is uniquely position to evaluate Allergan's claims.

Decision:

NAD determined that the claims at issue in this proceeding are within its purview of review. The FDA's mandate differs from that of the NAD, which is charged with ensuring that advertising claims, in the context in which they appear, are truthful and accurate such that consumers can make informed purchasing decisions. While the FDA has jurisdiction over the advertising and promotion of prescription pharmaceutical products, FDA jurisdiction does not preclude NAD from providing self-regulatory guidance on the challenged advertising, particularly whether the challenged advertising for Trulance communicates a misleading message about competing products. Given that the advertiser has elected not to participate in this NAD inquiry, NAD will refer this matter to the appropriate regulatory authorities pursuant to Section 2.10(B) of *NAD/NARB Procedures*. **(#6130 RL, referred to government 11/01/2017)**